

Appl. Serial No. 09/748,405
Docket No.: GUID.024US01
Amendment and Response

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REMARKS

The final Office Action mailed July 31, 2003 has been received and carefully reviewed. Claims 1-20 are pending in the application. None of the claims have been amended. Reconsideration of the application and withdrawal of the rejections are respectfully requested.

Claims 1-5 and 7-20 were rejected under 35 U.S.C. § 102(b) as being anticipated by *Bednarek, et al.* (US 6,120,500). Applicant respectfully contends that *Bednarek*, as asserted, is a 102(e) reference, a not a 102(b) reference. Claim 6 was rejected under 35 U.S.C. § 103(a) as being unpatentable over *Bednarek* in view of *Sugita et al.* (US 4,969,890).

The Examiner contends that *Bednarek* teaches an apparatus having an elongated shaft (22), with proximal and distal sections, a first lumen 33, a distal tip which has an opening 40 providing exterior access to, and in fluid communication with the first lumen 33 and which is oriented at an angle (J-shaped) with respect to a longitudinal axis of the shaft (22). It is further contended that *Bednarek* teaches a guide member 39 within the shaft (22), and a stabilizing member 16 deployable outside the tubular shaft (22), with an electrical connector at the proximal portion of the shaft. Reference is made to column 11 and Figure 11, which the Examiner contends shows an elongated shaft (22) with multiple lumens.

Bednarek teaches a rail catheter ablation and mapping system. The system described in *Bednarek* is used to perform ablation procedures in the left atrium. Left atrial access is accomplished transseptally from the right atrium. *Bednarek* particularly teaches that a "transseptal introducer is then advanced into the right atrium through the hemostasis introducer and over the guidewire. A conventional transseptal technique is used for approach into the left atrium of the heart. The guidewire is used to provide a path from the left atrium transseptally

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back through the hemostasis valve after the transseptal technique has been performed" (column 12, lines 10-16).

The apparatus disclosed in *Bednarek* differs from Applicant's claimed system in several ways. Initially, *Bednarek* fails to teach a guide member which has a distal extremity or means configured for entry into a coronary sinus ostium, as is recited in Applicant's independent claims 1, 17, 18, 19, and 20.

In the Office Action, the Examiner contends that *Bednarek* teaches a "guide member 39 within the shaft." Respectfully, Figure 11 and supporting text indicate that element 39 is a lumen of ablation catheter 20 (see column 10, lines 25-30). Clearly, element 39 is a structure very different from the guide member or guide means recited in Applicant's claims. Moreover, the guidewire described in *Bednarek* is employed to provide a path from the left atrium transseptally to the right atrium, and is not described as useful for locating vessels, such as by incorporation of a distal extremity configured to access such vessels.

Functional

The Examiner further contends that *Bednarek* discloses an elongated shaft (22) having a distal tip that has an opening 40 providing exterior access to, and in fluid communication with, the first lumen 33. Reference is made to the partial cross-sectional drawing of Figure 11.

Respectfully, element 40 does not appear to be an opening, as is contended by the Examiner. Rather, element 40 is described as the distal tip of the slotted sheath 22, and the opening or slot 30 is proximal to element 40. *Bednarek* teaches, at column 9, lines 13-21, that "in a preferred embodiment, as shown in FIG. 9, the rail (16) extends through the lumen (15) of the outer guiding introducer (14), out the opening or slot (30) and then loops back through a lumen (23) within the slotted sheath (22) as is shown in FIG. 11. However, the rail need not extend through the entire length of the slotted sheath (22) and may exit through the side of the slotted sheath (22) at a location (25) proximal from the distal end (40) of the slotted sheath (22).

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Further, it is unclear from the Office Action or the asserted reference how the distal tip 40 can be oriented at an angle with respect to a longitudinal axis of the elongated shaft. Using the Examiner's characterization of the elements shown in Figure 11 of *Bednarek*, the distal tip 40 (which does not have an opening as discussed above) is the distal tip of slotted sheath 22. As such, the longitudinal axis passing through the distal tip 40 is parallel with that of the slotted sheath 22. Because the distal tip 40 and slotted sheath 22 share the same longitudinal axis, it is unclear how the distal tip 40 can be oriented at an angle with respect to the longitudinal axis of the slotted sheath 22.

Bednarek fails to teach other features recited in Applicant's claims. For example, *Bednarek* fails to disclose an elongated shaft having a first distal tip opening through which a guide member may be advanced and a second distal tip opening through which a support member may be advanced into a heart chamber, such as is recited in various forms in independent claims 14 and 20. *Bednarek* teaches a stabilizing member 16 which passes out of opening or slot 30 (Figure 11) or a location 25 (Figure 9) proximal to distal end 40. Assuming the Examiner is characterizing the stabilizing member 16 as teaching Applicant's recited stabilizing member or means in the claims, *Bednarek* does not teach another opening that provides for passage of a guide member.

To anticipate a claim, the asserted reference must teach every element of the claim. A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. The identical invention must be shown in as complete detail as is contained in the claim. All claim elements and their limitations must be found in the prior art reference to maintain a rejection based on 35 U.S.C. §102.

Bednarek fails to disclose, either expressly or inherently, several elements of Applicant's independent and dependent claims. *Bednarek* clearly does not teach the identical invention in as complete detail as is recited in Applicant's

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claims. For at least these reasons, the Examiner's rejection of claims 1-5 and 7-20 cannot reasonably be sustained.

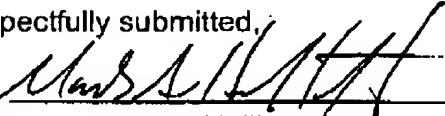
In paragraph 2 on page 3 of the Office Action, claim 6 was rejected under 35 U.S.C. § 103(a) as being unpatentable over *Bednarek* in view of *Sugita*. The Examiner asserts that *Sugita et al.* teaches a guide wire with a plurality of indicia to measure axial movement.

Applicant asserts that the combination of *Bednarek* and *Sugita* fails to teach Applicant's invention recited in claim 6. The arguments presented above in connection with the Examiner's rejection of claim 1 under 35 U.S.C. § 102(b) as being anticipated by *Bednarek* are reasserted with respect to the Examiner's rejection of claim 6. *Sugita et al.* does not cure the deficiencies of *Bednarek*, therefore claim 6 is patentable over the combination of *Bednarek* and *Sugita*.

It is believed that, in view of the arguments above, claims 1-20 are in condition for allowance. The Examiner is invited to contact Applicant's Representatives, at the below-listed telephone number, if there are any questions regarding this Response, or if prosecution of this application may be assisted thereby.

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